FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA and 5 CFR 1320.13. The information is needed immediately to implement section 506 of the act, which requires the agency to facilitate development and expedite the review of new drug products, including biological products, intended to treat a life-threatening or serious condition and that demonstrate a potential to meet an unmet medical need. The use of normal information clearance procedures would be likely to result in the prevention or disruption of this collection of information because section 112(b) of FDAMA requires FDA to issue guidance on fast track policies and procedures no later than November 21, 1998, i.e., within 1 year of the date of enactment of FDAMA.

Dated: October 14, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–28305 Filed 10–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0893]

Great Lakes Chemical Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Great Lakes Chemical Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of siloxanes and silicones, methyl hydrogen, reaction products with 2,2,6,6-tetramethyl-4-(2-propenyloxy)piperidine as an ultraviolet (UV) stabilizer for high density polyethylene and polypropylene intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8B4633) has been filed by Great Lakes Chemical Corp., c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in § 178.2010 Antioxidants and/or stabilizers for polymers (21 CFR 178.2010) to provide for the safe use of siloxanes and silicones, methyl hydrogen, reaction products with 2,2,6,6-tetramethyl-4-(2-propenyloxy)piperidine as a UV stabilizer for high density polyethylene and polypropylene intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: October 6, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–28149 Filed 10–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0194]

Agency Information Collection Activities; Announcement of OMB Approval; Registration of Cosmetic Product Establishment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Registration of Cosmetic Product Establishment'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 30, 1998 (63 FR 40718), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0027. The approval expires on October 31, 2001.

Dated: October 14, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–28220 Filed 10–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Antibody to Human T–Cell Lymphotropic Virus Type II (HTLV–II) Reference Panel 1; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a new FDA reference panel for tests intended to detect antibody to human T–cell lymphotropic virus Type II (HTLV–II Reference Panel 1). The HTLV–II Reference Panel 1 is used for the qualitative and semiquantitative evaluation of in vitro tests to detect antibody to HTLV–II in human serum or plasma. The HTLV–II Reference Panel 1 is designed to provide a release criterion for lots of HTLV–II antibody detection kits produced by licensed manufacturers of such tests and should not be used for experimental or other reference purposes.

DATES: The HTLV–II Reference Panel 1 was made available to the licensed manufacturers on June 4, 1998.

FOR FURTHER INFORMATION CONTACT: Charles O. Roberts, Center for Biologics Evaluation and Research (HFM–323), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–6721.

SUPPLEMENTARY INFORMATION: The HTLV–II Reference Panel 1 is a regulatory test panel intended for lot release testing of enzyme-linked immunosorbent assay (ELISA) HTLV–II antibody test kits produced by licensed manufacturers. The HTLV–II Reference Panel 1 consists of eight samples, six of which are reactive for antibody to HTLV–II. These reactive sera have been prepared by diluting known positive sera into a pool of normal human sera negative for antibodies to HTLV–II. Three of the diluted samples are expected to be repeatedly reactive for antibodies to HTLV–II by ELISA and three have borderline ELISA reactivity. The Center for Biologics Evaluation and